PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB2004/005210	08.12.2004	08.12.2003

International Patent Classification (IPC) or both national classification and IPC
G01N33/68

Applicant
OXFORD GENE TECHNOLOGY IP LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/GB2004/005210

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	19
	No:	Claims	1-18, 20-24
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-24
Industrial applicability (IA)	Yes:	Claims	1-24
	No:	Claims	

2. Citations and explanations

see separate sheet

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

International application No.

PCT/GB2004/005210

The following documents (D) are referred to in this opinion; the numbering will be adhered to the rest of the procedure:

D1: AMERICAN SOCIETY FOR MASS SPECTROMETRY 8, 1997, PAGES 25-31
D2: RAPID COMMUNICATIONS IN MASS SPECTROMETRY 14, 2000, PAGES 924-929
D3: JOURNAL OF MASS SPECTROMETRY 37, 2002, PAGES 223-229

1. NOVELTY (ARTICLE 33(2) PCT)

1.1 Claims 1-18 and 20-24 are anticipated by D1 to D3 and are therefore not novel.

D1 (abstract; page 26, right column, last paragraph; Page 27, right column first paragraph) describes N-acetylated peptides ("label" according to claim 15) and treated with trypsin. The peptide RLAIFSC*FR contains a deprotonated cysteic acid residue ("label", "arginine", "can form both a stabilised ion species and a protonated ion molecular species" according to claims 1, 3, 15 and 24) which balances the charge of one protonated residue, so that a further proton is incorporated without a favoured site. They were analysed using mass spectrometry ("system", "computer program" according to claims 20, 22).

D2 (abstract; Figure 2) describes the derivatisation ("label" according to claim 15) of the fibrino peptide A ("including an arginine" according to claim 15) with sulphonic acid and the sequence analysis by electro spray mass spectrometry, including single and double protonated forms ("ion species and a protonated ion molecular species that differ by one average mass unit" according to claim 15).

D3 (abstract) describes the deconvolution and deisotoping of electro spray mass spectra ("method of analysing a deisotoped peptide" according to claim 23).

1.2 The subject matter of claim 19 is not disclosed in the prior art documents and can therefore be considered as novel.

Inventive Step (Article 33(3) PCT)

Claim 19, relating to a kit comprising a label for derivatisation, is not based on an inventive concept, since it would be obvious for the skilled person to bring together in the form of a kit, the components needed to carry out non-inventive methods. A kit for a noninventive method itself is thus not inventive.